

# EXHIBIT 1

Q&A for Comirnaty (COVID-19 Vaccine mRNA) | FDA:

How is Comirnaty (COVID-19 VACCINE, mRNA) related to the PFIZER-BIONTECH COVID-19 VACCINE?

The FDA-approved Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses.

-----

From: PRESTON, ROBERT J II SES USAF AF/JA Civil Law and Litigation  
<robert.preston.8@us.af.mil>

Date: Wednesday, Sep 01, 2021, 20:51

To: BANNISTER, SHARON R Maj Gen USAF HAF AF/SG 3/4

<sharon.bannister@us.af.mil>

Cc: PLUMMER, CHARLES L Maj Gen USAF HAF AF/AF/JA <charles.plummer@us.af.mil>, DEGOES, JOHN J Maj Gen USAF HAF AF/SG <john.degoes@us.af.mil>, BLAKE, ROBERT M Brig Gen US Air Force HAF AF/A3O <robert.blake@us.af.mil>

Subject: RE: (ACTION) COVID-19 Risk

General

The wording of the FDA update removed the "legal distinction" language, but continues to reference the Pfizer-BioNTech Covid 19 Vaccine as being approved under a EUA. This remains a potential source of confusion and creates risk that objectors to the vaccine will seek to litigate the matter by claiming that versions of the vaccine carrying the Pfizer-BioNTech Covid 19 label cannot be mandated because they are merely authorized under the EUA and not FDA approved.

In discussions with the Assistant Deputy General Counsel (OSD Personnel and Health Policy), he acknowledged this remaining risk in the now-updated FDA guidance. However, based on those discussions we do not anticipate further clarification at least from OSD so I think we are in a position of having to move out with the guidance as is. As the vaccines are different in name only, there is not a legitimate safety or health issue with respect to the labels so it is perfectly appropriate to forge ahead. I merely bring the matter to your attention so that we are all on the same page as to the fact that FDA's updated language may not have mitigated the risk as much as we would like.

---

As to working towards a consistent message to the field, I would recommend an update along the following lines:

Questions have arisen about the use of the Pfizer-Biotech COVID vaccine stocks which have been produced under two labels: COMIRNATY and COVID-19 Vaccine. As paragraph 4 of the SECDEF's 24 August 2021 memo states vaccines will be administered "in accordance with FDA-approved labeling and guidance," we are required to rely on the FDA's latest guidance with the respect to the vaccines.

FDA's most recent guidance states that the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series (<https://www.fda.gov/media/144414/download>). Therefore, it is DoD's position that Pfizer-Biotech doses labeled "COMIRNATY" or "COVID-19 Vaccine" can be used interchangeably and can be administered on a mandatory basis IAW DoD and AF guidance/policy.

Thank you

v/r

Rob Preston

ROBERT J. PRESTON II, SES, USAF  
Director, Civil Law and Litigation  
The Judge Advocate General's Corps